REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

The specification has been amended to make editorial changes, in response to the Examiner's request. No new matter has been added as a result of these amendments.

Claim 1 has been amended to recite that the Chinese herbal medicine is present in an amount less than 60 w/w% per total amount of the composition, and wherein the base comprises a combination of carrageenan, carob bean gum and xanthan gum. Support for this amendment can be found on page 6, lines 26-28, Examples 1-4 and Table 1-1 on page 16 of Applicants' specification.

Claim 2 has been amended to recite that the composition comprises 0.01 to 10.0 w/w % carrageenan, 0.01 to 10.0 w/w % carob bean gum and 0.01 to 10.0 w/w % xanthan gum, per total amount of the composition. Support for this amendment can be found on page 5, lines 24-26, page 6, lines 7-10 and 18-20 of Applicants' specification.

No new matter has been added to the application by the above-discussed amendments.

The rejection of claims 1 and 2 as being indefinite under 35 U.S.C. § 112, second paragraph is respectfully traversed.

The Examiner takes the position that the composition in the form of jelly containing "Chinese herbal medicine" is indefinite because the metes and bounds of the claims are unclear. The Examiner requests that the term be defined.

Applicants respectfully disagree with the Examiner's position. MPEP 2173.02 states that the definiteness of claim language must be analyzed, not in a vacuum, but in light of the specification, the teachings of the prior art and the interpretation which would be given to the claim by one of ordinary skill in the art. Applicants' invention is not limited by the particular Chinese herbal medicine chosen, as is explained on page 8, lines 8-10 of Applicants' specification. Furthermore, page 8, lines 10-16 sets forth examples of ordinary Chinese herbal medicines. Thus, after considering the specification, one of ordinary skill in the art would understand the meaning of the term "Chinese herbal medicine", as recited in Applicants' claims.

Furthermore, MPEP 2173.04 states that the breadth of a claim is not to be equated with indefiniteness. Specifically, if the scope of the subject matter embraced by the claims is clear, then the claims comply with 35 U.S.C. 112, second paragraph. As stated above, the scope of Applicants' claims is clear, when analyzed in light of the specification and the interpretation of one of ordinary skill in the art.

For these reasons, the rejection of claims 1 and 2 is untenable, and should be withdrawn.

The patentability of the present invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Applicants' invention relates to a Chinese herbal medical composition in the form of jelly, which hardly causes syneresis, is superior in preservative stability, is broadly applicable to Chinese herbal medicine and is orally taken without taking care of the bitter taste of the medicine. More specifically, Applicants' invention relates to a Chinese herbal medical composition in the form of jelly, comprising a Chinese herbal medicine in a base, wherein the Chinese herbal medicine is present in an amount less than 60 w/w% per total amount of the composition, and the base comprises a combination of carrageenan, carob bean gum and xanthan gum. Further, the composition comprises 0.01 to 10.0 w/w% carrageenan, 0.01 to 10.0 w/w% carob bean gum and 0.01 to 10.0 w/w% xanthan gum, per total amount of the composition, and the base does not comprise a phosphate buffer.

The rejection of claims 1 and 2 under 35 U.S.C. § 102(b) as being anticipated by Ninomiya et al. is respectfully traversed.

The Examiner takes the position that Ninomiya et al. teach a medical composition in a jellied form containing carrageenan and xanthan gum, which does not contain a phosphate buffer.

The Ninomiya et al. reference relates to a jellied medical composition for oral administration which is easily taken by patients of advanced age or patients with dysphagia. The base of the jelly of Ninomiya et al. comprises carrageenan and locust (carob) bean gum, and preferably further contains polyacrylic acid or a partly neutralized product or a salt thereof.

Ninomiya et al. describe that as a base used in a jellied medical composition for oral administration, one or more selected from gelatin, pectin, xanthan gum, carrageenan, locust bean gum, mannan, etc. may be used, and the base containing carrageenan and locust bean gum is preferable. However, in the examples of the reference, only a combination of κ-carrageenan and locust bean gum is used.

MPEP 2131 states that for anticipation, the identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). Ninomiya et al. fail to set forth the identical invention, as recited in Applicants' claims. Specifically, Ninomiya et al. fail to teach a base comprising a combination of carrageenan, carob bean gum and xanthan gun. Even assuming *arguendo* that the reference is found to suggest varied components and combinations for the base of the jelly composition, any suggestion is overcome by the showing of unexpected results achieved by Applicants' particular composition, as discussed in detail below.

For these reasons, the invention of claims 1 and 2 is clearly patentable over Ninomiya et al.

The rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Aoi et al. is respectfully traversed.

The Examiner takes the position that Aoi et al. teach Chinese medicine mixed with a gelatinizing agent from carrageenan and a jelly without a phosphate buffer.

The Aoi et al. reference relates to a method for reducing bitterness of bitter and not readily ingestible substances often existing in drugs and foods by preparing a seasoned jelly by mixing a bitter substance with a gelatinizing agent and a seasoning agent.

As a gelatinizing agent, Aoi et al. describe agar, gelatin, κ-carrageenan, etc. MPEP 2131 states that a claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. As discussed above, Applicants have amended claim 1 to require that the base comprise a combination of carrageenan, carob bean gum and xanthan gum. The reference fails to teach or suggest this recited combination, and thus fails to anticipate Applicants' claim 1.

For these reasons, the invention of claim 1 is clearly patentable over Aoi et al.

The rejection of claims 1 and 2 under 35 U.S.C. § 103(a) as being unpatentable over Aoi et al. and Ninomiya et al. is respectfully traversed.

The Examiner relies on these references for the reasons stated above. Further, the Examiner asserts that the references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions to make a jelly. The Examiner further states combining two or more ingredients in order to form a third composition which is useful for the same purpose is obvious, and therefore one of ordinary skill in the art would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to encompass Chinese medicine.

Applicants' invention relates to a Chinese herbal medical composition in the form of jelly, wherein a Chinese herbal medicine is contained in a base comprising a combination of carrageenan, carob bean gum and xanthan gum. Ninomiya et al. fail to explicitly teach a combination of carrageenan, carob bean gum and xanthan gum in a base, free of phosphate buffer.

Furthermore, as shown in Comparative experiment B of the enclosed Rule 1.132 Declaration (hereafter "Declaration"), by using a combination of κ-carrageenan, carob bean gum and xanthan gum, the syneresis is drastically (unexpectedly) improved compared to a composition using only a combination of carrageenan and carob bean gum.

Thus, Applicants have demonstrated that the particular combination recited in the claims (carrageenan, carob bean gum and xanthan gum) has unexpected and superior results compared to the combination taught by the cited reference. One of ordinary skill in the art, reading the disclosure of Ninomiya et al., would not expect Applicants' recited combination to have superior results over another combination. As stated in MPEP 716.02(a)(III), evidence of a property not possessed by the prior art is evidence of nonobviousness.

Additionally, as shown in Comparative experiment A of the enclosed Declaration, by using a combination of κ-carrageenan, carob bean gum and xanthan gum, the syneresis is considerably improved compared to a composition using only κ-carrageenan, as taught by Aoi et al.

Applicants' recited combination of carrageenan, carob bean gum and xanthan gum results in superior unexpected properties over the teachings of the cited prior art.

For these reasons, the invention of claims 1 and 2 is clearly patentable over Ninomiya et al. and Aoi et al.

The rejection of claims 1 and 2 under 35 U.S.C. § 103(a) as being unpatentable over Takatsu in view of Young et al. and Ninomiya et al. is respectfully traversed.

The Examiner takes the position that Takatsu teaches jellied black jujubes, which is a Chinese herbal medicine. The Examiner admits that Takatsu fail to teach the claimed gelling agent. The Examiner states that Young et al. teach xanthan gum, carrageenan, and carob bean gum in a jelly, and Ninomiya et al. teach using iota, kappa and lambda carrageenan to gel medicinal compositions. The Examiner asserts that one of ordinary skill in the art would reasonably expect that these gelling agents taught by Young et al. and Ninomiya et al. could be used as the type of gelling agent in the composition of Takatsu.

Takatsu relates to a process for preparing a sweet jellied paste, produced by the steps of immersing dried fruits in water so as to obtain restored fruits and immersion water; adding either the restored fruits or strained restored fruits to agar liquor together with the immersion water and then mixing; and kneading the same to a final jellied paste. The object of this patent is to provide a new sweet jellied paste without adding sugar and a process for preparation thereof.

Accordingly, Takatsu is different from Applicants' invention in both the object of the invention, and the technical field of the invention. Further, as admitted by the Examiner, Takatsu fail to teach or suggest Applicants' recited base.

The Young et al. reference relates to a bakery shortening substitute that is an emulsion having a lipid phase and an aqueous phase, wherein the aqueous phase contains a gelling agent that is konjak. The reference further relates to the emulsion preparation method and bakery products that contain the emulsion as a reduced-fat shortening substitute. The object of Young et al. is the introduction of a reduced fat or a no-fat version of many fat-containing food products.

In the Young et al. reference, there is a description of carrageenan, carob bean gum and xanthan gum, as indicated by the Examiner. However, xanthan gum is used to

reduce fat levels by allowing increased water contents in the lower fat foods; carrageenan is added as a sizing agent of the emulsion; and carob bean gum is mixed as a thickener gum in aqueous phase. Furthermore, none of the passages of the reference referred to by the Examiner teach or suggest a base for a jellied composition comprising all three ingredients combined together, as required by Applicants' claims.

The comments concerning Niyomiya et al., as set forth previously, are equally applicable to this rejection.

The Examiner has relied upon Young et al. and Ninomiya et al. as teaching Applicants' recited base composition. However, as discussed above, neither Young et al. nor Ninomiya et al. teach or suggest the combination of carrageenan, carob bean gum and xanthan gum, as required by Applicants' claims. Therefore, the secondary references fail to remedy the deficiencies of the primary reference (Takatsu).

Furthermore, none of the references, taken alone or in combination, teach or suggested the surprisingly unexpected results achieved by Applicants' recited composition, as demonstrated in the enclosed Declaration.

For these reasons, the invention of claims 1 and 2 is clearly patentable over Takatsu in view of Young et al. and Ninomiya et al.

The rejection of claims 1 and 2 under 35 U.S.C. § 103(a) as being unpatentable over Sugai et al. in view of Young et al. and Ninomiya et al. is respectfully traversed.

The Examiner takes the position that Sugai et al. teach kudzu, Chinese medicine, in jelly. The Examiner admits that Sugai et al. fail to teach the claimed gelling agent. The Examiner states that Young et al. teach xanthan gum, carrageenan, and carob bean gum in a jelly, and Ninomiya et al. teach using iota, kappa and lambda carrageenan to gel medicinal compositions. The Examiner asserts that one of ordinary skill in the art would reasonably expect that these gelling agents taught by Young et al. and Ninomiya et al. could be used as the type of gelling agent in the composition of Sugai et al.

The Sugai et al. reference relates to cosmetics for application on the skin or eyes, and does not teach or suggest oral application. The Examiner states that the reference teaches a Chinese medicine. However, the plant extracts illustrated in the reference are used only in cosmetic compositions, such as anti-melanomagenic agents.

The heading for MPEP 2141.01(a) is "To Rely On A Reference Under 35 U.S.C. 103, It Must Be Analogous Prior Art." This section of the MPEP states that in order to rely on a reference as a basis for rejection of Applicants' invention, the reference must either be in the field of Applicants' endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned. See also *In re Oetiker*, 24 USPQ2d 1443 (Fed. Cir. 1992). Further, a reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. See also *Wang Laboratories Inc. v. Toshiba Corp.*, 26 USPQ2d 1767 (Fed. Cir. 1993).

The Sugai et al. reference is not an appropriate reference for use in an obviousness rejection for the reasons stated above. Specifically, as recited in the first paragraph of Applicants' specification, Applicants' invention relates to a composition which can be orally taken without taking care of the bitter taste of the Chinese herbal medicine. This is clearly a different field of endeavor than a cosmetic composition comprising a plant extract.

Furthermore, as admitted by the Examiner, Sugai et al. fail to teach or suggest Applicants' recited base component. Similar to the discussion above, the Examiner has relied upon Young et al. and Ninomiya et al. as teaching Applicants' recited base composition. However, as discussed above, neither Young et al. or Ninomiya et al. teach or suggest the combination of carrageenan, carob bean gum and xanthan gum, as required by Applicants' claims. Therefore, even if, *arguendo,* Sugai et al. is considered an appropriate reference for an obviousness rejection, the secondary references fail to remedy the deficiencies of the primary reference (Sugai et al.). Furthermore, none of the references, taken alone or in combination, teach or suggested the surprisingly unexpected results achieved by Applicants' recited composition, as demonstrated in the enclosed Declaration.

For these reasons, the invention of claims 1 and 2 is clearly patentable over Sugai et al. in view of Young et al. and Ninomiya et al.

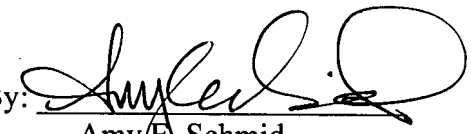
Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of objection and rejection set forth by the Examiner has been

overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

Tsunehiro FUKUCHI et al.

By: 

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Version with Marking to Show Changes Made

SPECIFICATION

CHINESE HERBAL MEDICAL COMPOSITION IN THE FORM OF JELLY

TECHNICAL FIELD OF THE INVENTION

The present invention relates to a Chinese herbal medical composition in the form of jelly, which hardly causes syneresis, is superior in the preservative stability, ~~especially~~ is broadly applicable to Chinese herbal medicine (漢方薬),~~(漢方薬)~~ and can be orally taken without taking care of the bitter taste, etc., of the Chinese herbal medicine.

BACKGROUND ~~ART~~OF THE INVENTION

The traditional Chinese herbal medicines are in the forms of liquids prepared by decocting crude drugs (生薬), powders prepared by powdering crude drugs or pills made of crude drugs and honey. Therefore ~~and therefore~~, traditional Chinese herbal medicines have the disadvantages of being inconvenient due to the time required to decoct~~have great demerits in respect of lacking in the conveniences due to taking times for decocting~~ crude drugs, and due to having to ~~preparing~~ prepare it according to necessity. Furthermore, it is painful or difficult for~~when~~ a patient ~~takes~~ to take the decoction or the powdered crude drug, ~~it is painful or difficult to take it~~ due to the bitter taste or smell, which are peculiar to ~~a~~ Chinese herbal medicines. ~~There were such problems peculiar to a Chinese herbal medicine.~~

~~Nowadays~~Today, in order to solve such problems, Chinese herbal medical preparations, such as extracts from a Chinese herbal medicine, powders, granules, tablets, liquids, etc., are prepared starting from the

powdered crude drugs ~~are used~~. These preparations solve the inconveniences due to taking time~~s for~~ to decoct ~~decocting~~ crude drugs, and ~~due to~~ having to prepare it according to necessity. These preparations~~, and that~~ are also superior in ~~the~~ preservative stability.

However, a patient must take several grams of preparation in the form of powders, granules or tablets, and ~~it~~ this is a burden for the patient. Further, ~~to take them much. In addition, in regard to~~ the powders and the granules can cause~~, there are such~~ problems such as ~~choke~~choking, resulting in a sandy feeling in a mouth, or getting between false teeth when they are taken. ~~In regard to the~~The tablets can be~~, they are~~ too large for a patient to take ~~them~~. The taste and smell peculiar to a Chinese herbal medicine is improved by tabletting it. However, there are still disadvantages in~~, but there are left some troubles such~~ that a Chinese herbal medicine is strongly tasted~~, and it~~ is unpleasant, and is ~~hardly~~ difficult to take ~~it~~ when the contents in the tablets dissolve, or the tablets disintegrate in a mouth while taking them.

On the other hand, ~~in regard to~~ the liquids ~~they~~ are more easily taken compared to~~comparing with~~ the powders, the granules and the tablets. However, the liquids have~~, but there are such~~ troubles in that the bitter taste and smell peculiar to a Chinese herbal medicine becomes strong, because the liquid is broadly spread in a mouth. Therefore ~~and therefore~~, it is painful and ~~hardly~~ difficult to take ~~it~~a liquid formulation. Furthermore, it is inconvenient to carry~~for carrying on~~ as it is packed in a glass-bottle. In order to solve such problems ~~on~~ with a Chinese herbal medical preparation, it is considered to make a Chinese herbal medicine in the form of jelly.

As a jelly preparation containing a Chinese herbal medicine, there

is known a jelly preparation made of a Chinese herbal medicine and gelatin (Japanese patent publication B 7-116049). As gelatin is a gelling agent which is physico-chemically unstable, the preparation lacks ~~in the~~ preservative stability and ~~it~~ must be stored in a cold place. Therefore, it does not stand for the test for medicines (the long term-preservation test at 25°C under 60 % RH for 3 years, or the accelerated preservation test at 40°C under 75 % RH for 6 months, etc.). In addition, gelatin is easily dissolved in a mouth and therefore, the preparation easily gives the bitter taste and is difficult to take~~lacks in easily taking~~ when a Chinese herbal medicine having the strong bitter taste is contained.

In addition, it is ~~considerable~~ considered that a jelly preparation containing Chinese herbal medicine is prepared ~~by~~ using sodium alginate or agar. As a jelly preparation containing a Chinese herbal medicine ~~by~~ using sodium alginate, ~~there is known~~ a jelly preparation containing Sho-saiko-to is known (小柴胡湯) (Japanese patent No.2508547). The bitter taste peculiar to a Chinese herbal medicine can be masked by adding alginic acid. However, as jelly containing alginic acid causes much syneresis ~~much~~, heterogeneity of the drug occurs and the drug remains in the packed vessel ~~remains~~ when taking it. The appearance is also bad. Therefore, the preparation is not preferable as a medicine.

In regard to a jelly preparation prepared ~~by~~ using agar, the preparation causes much syneresis, similar to ~~much as well as~~ the preparation containing alginic acid. Further ~~and further~~, the preparation easily disintegrates in a mouth, easily gives the bitter taste and does not give a good feeling when taking it.

As other jelly preparations, a jelly composition (Japanese patent

publication A 9-187233 and Japanese patent publication A 9-194346) and a Chinese herbal medical composition in the form of jelly (Japanese patent publication A 2001-114696) are known, but it is very difficult ~~especially~~ to prepare jelly preparations containing a Chinese herbal medicine which guarantees the preservative stability on a medical level.

The following reasons are considered as~~As~~ causes ~~hard~~ which make it difficult to make a Chinese herbal medicine in the form of jelly.~~, the following reasons are considered.~~

The preparation contains as a starting material, a natural product which consists of a variety of ingredients, and many of these ingredients are structurally unknown. In addition, ~~in the forms as the starting material,~~ there are many ~~kinds~~ forms of starting materials, such as crude drugs, liquid extract, condensed extract, dry extract, soft extract, fluid extract, etc., and the dosages on them ~~are various~~vary.

As there is such a ~~back ground~~background peculiar to a Chinese herbal medicine, when a Chinese herbal medicine is formed into a jelly preparation, according to the kind or amount of the contained Chinese herbal medicine~~ or its amount~~, there are possibilities to produce the preparation wherein its appearance can not be maintained due to syneresis and the stability of the active ingredients can not be maintained. Therefore, a Chinese herbal medical composition in the form of jelly which is broadly applicable ~~to~~ has been desired.

~~DISCLOSURE~~ BRIEF SUMMARY OF THE INVENTION

The present invention was completed based on the above viewpoint and ~~its~~ the goal is ~~problem is~~ to provide a Chinese herbal medical composition in the form of jelly, which hardly causes syneresis, is superior in the preservative stability, ~~especially~~ is broadly applicable

to a Chinese herbal medicine, and is orally taken without taking care of the bitter, etc., of a Chinese herbal medicine.

The present inventors have ~~been~~ extensively studied to solve the above problems, and have~~it has been~~ found that by using at least one substance selected from the group consisting of carrageenan, carob bean gum and xanthan gum as a base (not containing phosphate buffer) of the jelly preparation containing a Chinese herbal medicine, a Chinese herbal medical composition in the form of jelly, which hardly causes syneresis, is superior in the preservative stability, ~~especially~~ is broadly applicable to a Chinese herbal medicine, and is orally taken without taking care of the bitter, etc., of a Chinese herbal medicine is obtainable. Thus, the present invention was completed.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a stick-like packed vessel which is sealed on three parts.

Explanation of signs

1: A Chinese herbal medical composition in the form of jelly

2: Sealed parts

~~PREFERABLE MODE FOR CARRYING OUT THE INVENTION~~DETAILED DESCRIPTION OF THE INVENTION

Carrageenan used in ~~a~~ the Chinese herbal medical composition in the form of jelly of the present invention is not limited as long as it is usually used for a jelly composition. For example, there are κ (kappa) type, ι (iota) type and λ (lambda) type, with ~~in~~ respect to carrageenan. Any type is usable, but preferably a combination of ι type carrageenan and either κ type carrageenan or λ type carrageenan, or a combination

of these three type carageenans, or ι type carrageenan solely is usable. When a combination of ι type carrageenan and either κ type carrageenan or λ type carrageenan, or a combination of these three type carageenans is used, ι type carrageenan is usually used in the amount of more than 50 w/w % per total carageenan weight, preferably more than 70 w/w %, and more preferably more than 95 w/w %.

The amount of carageenan contained in ~~a~~ the Chinese herbal medical composition in the form of jelly of the present invention is preferably 0.01~10.0 w/w % per total amount of the composition, more ~~preferable~~ preferably 0.05~5.0 w/w %, and further more preferably 0.08~2.0 w/w %. When the amount of carrageenan is beyond the above range, the preparation becomes too viscous to prepare it, and when the amount is below the above range, the jelly formation becomes difficult and the desired composition is not obtainable.

Carob bean gum used in ~~a~~ the Chinese herbal medical composition in the form of jelly of the present invention is not limited as long as it is usually used for a jelly composition.

The amount of carob bean gum contained in ~~a~~ the Chinese herbal medical composition in the form of jelly of the present invention is preferably 0.01~10.0 w/w % per total amount of the composition, more ~~preferable~~ preferably 0.05~5.0 w/w %, and further more preferably 0.1~2.0 w/w %. When the amount of carob bean gum is beyond the above range, the preparation becomes too viscous to prepare it, and when the amount is below the above range, the jelly formation becomes difficult and the desired composition is not obtainable.

Xanthan gum used in ~~a~~ the Chinese herbal medical composition in the form of jelly of the present invention is not limited as long as it is usually used for a jelly composition.

The amount of xanthan gum contained in ~~a~~ the Chinese herbal medical composition in the form of jelly of the present invention is preferably 0.01~10.0 w/w % per total amount of the composition, more ~~preferable~~ preferably 0.05~5.0 w/w %, and further more preferably 0.08~2.0 w/w %. When the amount of xanthan gum is beyond the above range, the preparation becomes too viscous to prepare it, and when the amount is below the above range, the jelly formation becomes difficult and the desired composition is not obtainable.

The amount of a Chinese herbal medicine contained in ~~a~~ the Chinese herbal medical composition in the form of jelly of the present invention is preferably less than 60 w/w % per total amount of the composition, more ~~preferable~~ preferably less than 50 w/w %, and further more preferably less than 30 w/w %. When the amount of the Chinese herbal medicine is beyond the above range, there is a possibility that the preparation becomes too viscous to prepare it and the jelly formation becomes difficult due to it being rice cake or jam-like.

A dispersion medium in order to disperse a base which is used for a Chinese herbal medical composition in the form of jelly of the present invention includes a liquid which is usually used as a dispersion medium of a jelly composition, for example water or a mixture of water and a polyalcohol. Examples of the polyalcohol are glycerin, propylene glycol, etc. The amount of the dispersion medium of a Chinese herbal medical composition in the form of jelly of the present invention is, preferably 30~90 w/w % per total composition, more preferably 30~85 w/w %, and further more preferably 40~80 w/w %.

The Chinese herbal medical composition in the form of jelly of the present invention may, if necessary, contain various known ingredients which are acceptable as medical additives and are orally administrable,

such as stabilizing agents, correctives, sweetening agents, emulsifying agents, dispersion agents, preservatives, flavors, coloring agents, etc.

The stabilizing agent, if desired, contained in the Chinese herbal medical composition in the form of jelly of the present invention includes ascorbic acid, disodium edetate, tocopherol, etc. The corrective includes citric acid, malic acid, lactic acid, succinic acid, tartaric acid, ascorbic acid, a citrate, a malate, a lactate, a succinate, a tartarate, etc. The sweetening agent includes glucose, fructose, saccharin sodium, sucrose, D-sorbitol, D-mannitol, hydrogenated maltose starch syrup, etc. The emulsifying agent includes polyoxyethylene sorbitan monooleate, sodium lauryl sulfate, etc. The dispersion agent includes an aqueous high molecular weight compound, such as carboxymethylcellulose, sodium alginate, hydroxypropylcellulose, hydroxyethylcellulose, etc. The preservative includes methyl parahydroxybenzoate (methylparaben), ethyl parahydroxybenzoate (ethylparaben), etc. The flavor includes ones such as menthols, fruit juices, or essential oils. The coloring agent includes caramel, etc.

The raw material contained in the Chinese herbal medical composition in the form of jelly of the present invention is not limited as long as it is an ~~ordinal~~ ordinary Chinese herbal medicine. For example, Kakkon-to (葛根湯), Sho-seiryu-to (小青竜湯), Sho-saiko-to (小柴胡湯), Hachimi-jio-gan (八味地黄丸), Hochu-ekki-to (補中益気湯), Sho-kenchu-to (小建中湯), Shofu-san (消風散), Seijo-bofu-to (清上防風湯), Bofu-tsusho-san (防風通聖散), Gorei-san (五苓散), Boi-ogi-to (防已黄耆湯), Otsuji-to (乙字湯), Toki-shakuyaku-san (当帰芍薬散), Keishi-bukuryo-gan (桂枝茯苓丸), Anchu-san (安中散), Heii-san (平胃散), etc., are illustrated. Further, a variety of Chinese herbal medicines are usable as well. The raw

material is not only limited ~~in~~ to Chinese herbal medicines, but also the raw material made of natural plants is usable in the -Chinese herbal medical composition in the form of jelly of the present invention. The raw material selected from Chinese herbal medicines and natural plants is usable in combination with other active substances in the Chinese herbal medical composition in the form of jelly of the present invention. For example, a combination of a cold medicine, an antitussive, an expectorant, and/or a medicine for stomach with a western medicine is usable.

The raw material is not limited as long as it is a usual Chinese herbal medicines or natural plants. For example, a crude drug, liquid extract, condensed extract, dry extract, soft extract, fluid extract, etc., are illustrated. The amount of the raw material may be contained in order that the suitable dosage is obtained when a Chinese herbal medical composition in the form of jelly is taken in the defined amount.

The method for preparing the Chinese herbal medical composition in the form of jelly of the present invention can be the same manner as in a usually known method for jelly preparations. For example, the suitable amount of warmed water as a dispersion medium is added to a base and a raw material and if necessary, a desired substance, and the mixture is stirred to be dispersed, dissolved or suspended, or otherwise the suitable amount of water or cold water as a dispersion medium is added to a base and a raw material and if necessary, a desired substance at room temperature. The mixture is stirred under warming to be dispersed, dissolved or suspended and the resulting drug is cooled to prepare the Chinese herbal medical composition in the form of jelly. Further, when an ingredient which is not preferable to be exposed to high temperature is contained among a base and a raw material and if

necessary, a desired substance, it may be added after the dispersion, the solution or the suspension prepared above is adjusted ~~-~~to moderate temperature to prepare the Chinese herbal medical composition in the form of jelly. Otherwise~~, or otherwise~~ an ingredient which ~~it~~ is not preferable to be exposed to high temperature may be added thereto just before cooling to prepare the Chinese herbal medical composition in the form of jelly.

The packed vessel for the Chinese herbal medical composition in the form of jelly of the present invention is not specifically limited, but a stick-like vessel or a bag-like vessel is preferable in respect of carrying and taking it.

Examples

The present invention is explained by following examples and is not limited by these examples.

Examples 1~4 and Comparative examples 1~6

In regard to Examples 1~4 and Comparative examples 1, 5 and 6, the ingredients shown in Tables 1-1 and 1-2 were weighed and each ingredient was dissolved under heating at 80°C. The resulting solution was poured into a stick-like vessel sealed at three parts and cooled to prepare a Chinese herbal medical composition.

In regard to Comparative examples 2~4, after ~~previously~~ sodium alginate was homogenously dissolved in water, it was warmed at 50~60°C, and thereto were added aqueous dry extract of Kakkon-to (葛根湯). After the mixture was ~~homogenously~~ homogeneously dissolved for about 5 minutes, other residual ingredients were added thereto and stirred homogeneously~~homogenously~~. The mixture was poured into a stick-like vessel sealed at three parts and was cooled to prepare a

Chinese herbal medical composition.

The preparation of Example 1 ~~gave~~ resulted in a good Chinese herbal medical composition in the form of jelly, but the preparation of Comparative example 1 became like a rice cake without forming a jelly. The preparations of Examples 2~4 and Comparative example 5 ~~gave~~ resulted in Chinese herbal medical compositions in the form of jelly, but the preparations of Comparative examples 2~4 containing sodium alginate did not form jelly. The preparation of Comparative example 6 containing gelatin ~~gave~~ resulted in a Chinese herbal medical composition in the form of jelly in a refrigerator, but the preparation was a semi-solid at room temperature.

Examples 5~7

The ingredients shown in Table 2 were weighed and each ingredient was dissolved under heating at 80°C. The resulting solution was poured into a stick-like vessel sealed at three parts and was cooled to prepare a Chinese herbal medical composition in the form of jelly.

Examples 8~10 and Comparative examples 7~9

In regard to Examples 8~10 and Comparative examples 8 and 9, the ingredients shown in Table 3 were weighed and each ingredient was dissolved under heating at 80°C. The resulting solution was poured into a stick-like vessel sealed at three parts and was cooled to prepare a Chinese herbal medical composition in the form of jelly.

In regard to Comparative example 7, after ~~previously~~ sodium alginate was homogenously dissolved in water, it was warmed at 50~60°C, and thereto were added aqueous dry extract of Seijo-bofu-to (清上防風湯). After the mixture was homogeneously~~homogenously~~

dissolved for about 5 minutes, other residual ingredients were added thereto and stirred homogeneouslyhomogenously. The mixture was poured into a stick-like vessel sealed at three parts and was cooled to prepare a Chinese herbal medical composition in the form of jelly.

The preparations of Examples 8~10 gave aresulted in good Chinese herbal medical compositions in the form of jelly. The preparations of Comparative example 7 and Comparative example 8 containing sodium alginate and agar, respectively gave resulted in a Chinese herbal medical composition in the form of jelly. The preparation of Comparative example 9 containing gelatin gave resulted in a Chinese herbal medical composition in the form of jelly in a refrigerator, but the preparation was a semi-solid at room temperature. The preparation of Comparative example 9 was dissolved in a mouth and gave the bitter taste when it was taken, and did not give good feeling (see Table 7). The preparation did not serve as a medicine.

Measurement of the amount of syneresis and the strength of jelly

According to the method below, the Chinese herbal medical compositions in the form of jelly obtained were stored at 40°C under 75 % RH and at 25°C under 60 % RH, respectively. The amount of syneresis and the strength of jelly were measured on each sample and their appearances were observed.

The method for measuring the amount of syneresis

The method was carried out by standing on end of a stick-like packed vessel sealed at three parts into which a Chinese herbal medical composition in the form of jelly was poured (fig Fig. 1). The ratio of the weight of syneresis remained in the air portion per total amount was

calculated.

The method for measuring the strength on jelly

The method was carried out by taking out a Chinese herbal medical composition in the form of jelly (sample) from a stick-like packed vessel sealed at three parts (see ~~fig~~ Fig. 1) after it was stored at 25°C for 24 hours, and the sample was measured at 25°C using a tool below.

Measuring tool: Rheometer CR-200D (prepared by San Kagaku)

Measuring conditions: Pressed speed, 30mm/min

Pressure-sensitive axis: Cross section 5 x 40mm x height 15mm (Stainless)

Results

The results obtained on syneresis of the preparations in the form of jelly of Examples 2~4 and Comparative example 5 were shown in Table 4-1. The preparations of Examples 2~4 were stored both at 40°C under 75 % RH and at 25°C under 60 % RH, and they hardly showed syneresis and their appearances were good. On the other hand, the preparation of Comparative example 5 containing agar showed much syneresis ~~much~~ both at 40°C under 75 % RH and at 25°C under 60 % RH. Its appearance was bad and did not serve as a medicine.

The results obtained on the jelly strength on the preparations in the form of jelly of Examples 2~4 and the preparation of Comparative example 5 were shown in Table 4-2. Changes on the jelly strength on the preparations of Examples 2~4 were not observed under the preservation both at 40°C under 75 % RH and 25°C under 60 % RH. On the contrary, rapid increase of the jelly strength was observed on the

preparation Comparative example 5 containing agar under the preservation both at 40°C under 75 % RH and at 25°C under 60 % RH in one month.

The preparations of Examples 5~7 ~~gave a~~resulted in good Chinese herbal medical compositions in the form of jelly, hardly showed syneresis under the preservation conditions both at 0°C under 75 % RH and at 25°C under 60 % RH (see Table 5-1), their appearances were good and changes of the jelly strength on them were not observed (see Table 5-2).

The preparations of Examples 8~10 ~~gave a~~resulted in good Chinese herbal medical compositions in the form of jelly, hardly showed syneresis under the preservation conditions both at 0°C under 75 % RH and at 25°C under 60 % RH (see Table 6-1). Their appearances were good and changes of the jelly strength on them were not observed (see Table 6-2).

On the contrary the preparations in the form of jelly of Comparative examples 7 and 8 showed much syneresis under the preservation conditions both at 0°C under 75 % RH and at 25°C under 60 % RH (see Table 6-1). Their appearances were bad and the jelly strength on them was greatly changed in one month and they could serve as a medicine (see Table 6-2).

As mentioned above, it was ascertained that the Chinese herbal medical composition in the form of jelly of the present invention hardly shows syneresis for a long time and is superior in the preservative stability ~~comparing with~~compared to a jelly preparation containing either gelatin or sodium alginate as a base.

When sodium alginate is used as a base, the Chinese herbal medical composition in the form of jelly is obtained or not obtained

depending on the raw material. On the contrast, according to the present invention the good Chinese herbal medical composition in the form of jelly can be obtained regardless of the raw material.

Masking effect on bitter taste

By using Chinese herbal medical compositions in the form of jelly and a semi-solid preparation containing gelatin (Comparative example 9), which had the ingredients shown in Table 3, the organoleptic test was carried out. The panel tests were carried out by using 10 persons (5 males and 5 females) and the evaluation were shown as follows: ++ : too bitter to take one, + : bitter, ± : slightly bitter, − : scarcely bitter, −− : no bitter

A preparation which was prepared by dissolving aqueous dry extract of Seijo-bofu-to (清上防風湯) 7g in water (100g) was used as a control.

As shown in Table 7, in regard to the Control and the preparations of Comparative examples 8 and 9, almost all persons answered with "too bitter to take them" (Control and Comparative example 9: 10/10, Comparative example 8: 8/10). On the contrast, in regard to the preparation of Example 10, persons who answered with "too bitter to take it" and "bitter" were 3/10 and 7/10, respectively and these preparations showed better result comparing with the preparations of Control and Comparative examples 8 and 9.

The preparation of Comparative example 7 gave the almost same result as the preparation of Example 10, and persons who answered with "too bitter to take it" and "bitter" were 1/10 and 9/10, respectively. The preparation of Comparative example 7 like the preparation of Example 10 showed a better result than the aqueous solution (control),

jelly preparations containing agar and gelatin, respectively (Comparative example 8 and 9). Although it is known that the bitter taste is masked by adding sodium alginate to a bitter taste substance, it seems not to exhibit any masking effect as the extract was much.

In regard to the preparation of Example 9, persons who answered with "slightly bitter" were 7/10 and there was none who answered with "too bitter to take it". In regard to the preparation of Example 8, persons who answered with "slightly bitter" were 8/10 and there was none who answered with "too bitter to take it" or "bitter".

As mentioned above, it was ascertained that a Chinese herbal medical composition in the form of jelly wherein the bitter taste of a Chinese herbal medicine effectively masks was obtainable. Especially by solely using ι carrageenan, it was confirmed that the bitter taste of a Chinese herbal medicine which was contained in the high concentration was excellently masked. Furthermore, by adding a sweetening agent to the Chinese herbal medical composition in the form of jelly prepared by the present invention, it became possible to take it almost without taking care of the bitter taste of a Chinese herbal medicine.

Table 1-1

Ingredient	Amount (weight %)			
	Ex. 1	Ex. 2	Ex. 3	Ex. 4
Aqueous dry extract of Kakkon-to (葛根湯)	30	15	15	15
ι Carrageenan	0.5	1	1	-
κ Carrageenan	-	-	0.05	1

Carob bean gum	0.1	0.25	0.25	0.25
Xanthan gum	0.2	0.45	0.45	0.45
Sodium alginate	-	-	-	-
Calcium monohydrogen phosphate	-	-	-	-
Glucono-δ-lactone	-	-	-	-
Agar	-	-	-	-
Gelatin	-	-	-	-
Powdered hydrogenated maltose starch syrup	-	6	6	6
D-Sorbitol	-	6	6	6
Glycerin	-	6	6	6
Propylene glycol	-	1	1	1
Propyl parahydroxybenzoate	0.02	0.02	0.02	0.02
Purified water	69.18	64.28	64.23	64.28
Total	100	100	100	100

Table 1-2

Ingredient	Amount (weight %)					
	Comp. ex.1*	Comp. ex.2*	Comp. ex.3*	Comp. ex.4*	Comp. ex.5	Comp. ex.6*
Aqueous dry extract of Kakkon-to (葛根湯)	65	5	15	15	15	15
ι Carrageenan	0.5	-	-	-	-	-
κ Carrageenan	-	-	-	-	-	-
Carob bean gum	0.1	-	-	-	-	-
Xanthan gum	0.2	-	-	-	-	-
Sodium alginate	-	0.8	0.8	2	-	-
Calcium monohydrogen phosphate	-	0.2	0.2	0.5	-	-
Gluclono-δ-lactone	-	2.2	2.2	-	-	-
Agar	-	-	-	-	3	-
Gelatin	-	-	-	-	-	7.5
Powdered hydrogenated maltose starch syrup	-	-	-	-	-	-
D-Sorbitol	-	-	-	-	-	-
Glycerin	-	-	-	-	-	-
Propylene glycol	-	-	-	-	-	-
Propyl parahydroxybenzoate	0.02	0.02	0.02	0.02	0.02	0.02
Purified water	34.18	91.78	81.78	82.48	81.98	77.48
Total	100	100	100	100	100	100

* : not solidified

Table 2

Ingredient	Amount (weight %)		
	Ex. 5	Ex. 6	Ex. 7
Soft extract of Hachimi-jio-gan (八味地黄丸)	14	-	-
Keishi-bukuryo-gan (桂枝茯苓丸) (crude drug)	-	14	14
ι Carrageenan	1	1	1
κ Carrageenan	-	-	0.1
Carob bean gum	0.2	0.25	0.25
Xanthan gum	0.4	0.45	0.45
Powdered hydrogenated maltose starch syrup	6	6	6
D-Sorbitol	6	6	6
Glycerin	6	6	6
Propylene glycol	1	1	1
Propyl parahydroxybenzoate	0.02	0.02	0.02
Purified water	65.38	65.28	65.18
Total	100	100	100

Table 3

Ingredient	Amount (weight %)						
	Ex. 8	Ex. 9	Ex.10	Comp. ex. 7	Comp. ex. 8	Comp. ex. 9*	Control
Aqueous dry extract of Seijo-bofu-to (清上防風湯)	14	14	14	14	14	7	7
ι Carrageenan	1	1	-	-	-	-	-
κ Carrageenan	-	-	1	-	-	-	-
Carob bean gum	0.2	0.2	0.2	-	-	-	-
Xanthan gum	0.4	0.4	0.4	-	-	-	-
Sodium alginate	-	-	-	2	-	-	-
Calcium monohydrogen phosphate	-	-	-	0.5	-	-	-
Agar	-	-	-	-	3	-	-
Gelatin	-	-	-	-	-	7.5	-
Powdered hydrogenated maltose starch syrup	6	-	-	-	-	-	-
D-Sorbitol	6	-	-	-	-	-	-
Glycerin	6	-	-	-	-	-	-
Propylene glycol	1	-	-	-	-	-	-
Propyl parahydroxybenzoate	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Purified water	65.38	84.38	84.38	83.48	82.98	85.48	92.98
Total	100	100	100	100	100	100	100

* : not solidified

Table 4-1

Amount of syneresis (weight %)	40°C 75 % RH			
	Example 2	Example 3	Example 4	Comp. ex. 5
After 2 days	-	-	-	-
After one month	0.2 %	0.4 %	3.3 %	8.2 %
After 3 months	0.3 %	1.5 %	4.0 %	-
After 6 months	0.8 %	1.9 %	4.4 %	-
Amount of syneresis (weight %)	25°C 60 % RH			
	Example 2	Example 3	Example 4	Comp. ex. 5
After 2 days	no	no	2.3 %	3.0 %
After one month	0.4 %	0.6 %	5.0 %	9.2 %
After 3 months	1.2 %	2.0 %	4.8 %	-
After 6months	1.0 %	2.3 %	5.4 %	-

Table 4-2

Strength	40°C 75 % RH			
	Example 2	Example 3	Example 4	Comp. ex. 5
Before starting preservation	293g	300g	90g	143g
After one month	290g	314g	88g	191g
After 3 months	302g	322g	84g	-
After 6 months	297g	323g	86g	-
Strength	25°C 60 % RH			
	Example 2	Example 3	Example 4	Comp. ex. 5
Before starting preservation	293g	300g	90g	143g
After one month	285g	304g	87g	180g
After 3 months	297g	308g	88g	-
After 6 months	293g	322g	84g	-

Table 5-1

Amount of syneresis (weight %)	40°C 75 % RH			25°C 60 % RH		
	Ex. 5	Ex. 6	Ex. 7	Ex. 5	Ex. 6	Ex. 7
After 2 days	no	no	no	no	no	no
After one month	no	no	no	0.3 %	no	no
After 3 months	0.3 %	no	no	0.7 %	no	no
After 6 months	0.5 %	no	no	1.1 %	no	no

Table 5-2

Strength	40°C 75 % RH			25°C 60 % RH		
	Ex. 5	Ex. 6	Ex. 7	Ex. 5	Ex. 6	Ex. 7
Before starting preservation	163g	158g	160g	163g	158g	167g
After one month	189g	155g	161g	169g	158g	165g
After 3 months	182g	157g	164g	181g	160g	160g
After 6 months	180g	164g	166g	178g	159g	163g

Table 6-1

Amount of syneresis (weight %)	40°C 75 % RH				
	Ex. 8	Ex. 9	Ex. 10	Comp. ex. 7	Comp. ex. 8
After 2 days	-	-	-	-	-
After one month	0.2 %	0.2 %	4.2 %	9.0 %	10.0 %
After 3 months	0.5 %	0.4 %	5.2 %	-	-
After 6 months	0.8 %	0.5 %	5.0 %	-	-
Amount of syneresis (weight %)	25°C 60 % RH				
	Ex. 8	Ex. 9	Ex. 10	Comp. ex.7	Comp. ex.8
After 2 days	0.2 %	0.2 %	3.3 %	0.9 %	4.0 %
After one month	1.1 %	1.2 %	4.4 %	8.4 %	9.7 %
After 3 months	1.0 %	1.3 %	5.1 %	-	-
After 6 months	1.2 %	1.4 %	5.2 %	-	-

Table 6-2

Strength	40°C 75 % RH				
	Ex. 8	Ex. 9	Ex. 10	Comp. ex. 7	Comp. ex. 8
Before starting preservation	276g	109g	103g	105g	68g
After one month	292g	122g	100g	69g	153g
After 3 months	286g	118g	111g	-	-
After 6 months	-	296g	114g	-	-
Strength	25°C 60 % RH				
	Ex. 8	Ex. 9	Ex. 10	Comp. ex.7	Comp. ex.8
Before starting preservation	276g	109g	103g	105g	68g
After one month	287g	111g	114g	64g	139g
After 3 months	284g	110g	116g	-	-
After 6 months	282g	118g	118g	-	-

Table 7

Olganoleptic test	Evaluation (Unit: person)				
	++	+	±	-	--
Ex. 8	0	0	2	8	0
Ex. 9	0	3	7	0	0
Ex. 10	3	7	0	0	0
Comp. ex. 7	1	9	0	0	0
Comp. ex. 8	8	2	0	0	0
Comp. ex. 9	10	0	0	0	0
Control	10	0	0	0	0

++ : too bitter to take one

+ : bitter

± : slightly bitter

- : scarcely bitter

-- : no bitter

INDUSTRIAL APPLICABILITY

In the present invention, by using at least one substance selected from the group consisting of carrageenan, carob bean gum and xanthan gum as a base (not containing phosphate buffer) of the jelly preparation containing a Chinese herbal medicine, a Chinese herbal medical composition in the form of jelly, which hardly causes syneresis, is superior in the preservative stability, ~~especially~~ is broadly applicable to a Chinese herbal medicine, and is orally taken without taking care of bitter, etc., of a Chinese herbal medicine is obtainable. Furthermore, even when the Chinese herbal medical composition in the form of jelly of the present invention can stand for the test for medicines, for example the long term-preservation test at 25°C under 60 % RH for 3 years, and the accelerated preservation test at 40°C under 75 % RH for

6 months and is guaranteed in the preservative stability.

ABSTRACT

A Chinese herbal medical composition in the form of jelly, wherein a Chinese herbal medicine is contained in a base containing at least one substance selected from the group consisting of carrageenan, carob bean gum and xanthan gum and not containing phosphate buffer. The Chinese herbal medical composition, ~~which~~ hardly causes syneresis, is superior in the preservative stability, ~~especially~~ is broadly applicable to a Chinese herbal medicine and is orally taken without taking care of the bitter of a Chinese herbal medicine.